SECTION L – INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

The following information is specific to this solicitation and is provided to supplement and/or complete the associated ITEMS presented at the SECTION L website at http://rcb.cancer.gov/rcb-internet/wkf/sectionl.pdf.

I. General Information

Item 2: **Alternate I, of FAR Clause 52.215-1, INSTRUCTIONS TO OFFERORS-COMPETITIVE ACQUISITION**, is applicable to this solicitation.

Item 5: **JUST IN TIME PROCEDURES** are applicable to this solicitation.

The submission of an acceptable subcontracting plan **[X]** is, **[ ]** is not required.

If a subcontracting plan is required:

[X] It will be requested from only those offerors in the competitive range.
[ ] It will be requested from only the apparent successful offeror.
[ ] It WILL NOT be submitted in accordance with the JUST IN TIME procedures, therefore, a subcontracting plan will be requested from all offerors at the time of original submission in accordance with Alternate II, of FAR Clause 52.219-9, SMALL BUSINESS SUBCONTRACTING PLAN which is incorporated by reference.

Item 9: **NAICS CODE AND SIZE STANDARD:**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The NAICS Code is 541710
(2) The small business size standard is 500 employees.

Item 10: **THIS REQUIREMENT IS NOT SET ASIDE FOR SMALL BUSINESS** is applicable to this solicitation.

Item 11: **NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SMALL DISADVANTAGED BUSINESS CONCERNS.**

Offerors will be evaluated by adding a factor of 10% to the price of all offers, except offers from disadvantaged business concerns that have not waived the adjustment.

Item 12: **TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

It is anticipated that five awards will be made for this solicitation and that the awards will be made on or about September 30, 2005.

It is anticipated that the awards from this solicitation will be multiple-year, Cost-Reimbursement type completion contracts, each with a five year period of performance. Incremental funding will be used. [See Section L, PART IV-Business Proposal Instructions.]

Item 14: **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 70,728 labor hours

for the 5 year effort for all contracts awarded. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

Item 17: **COMPARATIVE IMPORTANCE OF PROPOSALS**

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are [significantly more important than cost or price/approximately equal to cost or price/significantly less important than cost or price]. The relative importance of the evaluation factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

Item 21: **LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70** is applicable to this solicitation.

II. General Instructions

Item 24: **Potential Award Without Discussions** is applicable to this solicitation.

Item 30: **Sharing Research Data** is applicable to this solicitation.

Item 34: **Small Business Subcontracting Plan** is applicable to this solicitation and the following information is provided to supplement this item to assist in proposal preparation:

The anticipated minimum subcontracting goals for this RFP are as follows:

20% for Small Business; 3% for Small Disadvantaged Business; 3% for Women-Owned Small Business; 2% for HUBZone Small Business; and 1.5% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

Item 36: **Extent of Small Disadvantaged Business Participation** is applicable to this solicitation.

Item 37: **Salary Rate Limitation in Fiscal Year 2005** is applicable to this solicitation.

Item 40: **Past Performance Information** is applicable to this solicitation and the following information is provided to supplement this item to assist in proposal preparation:

Past Performance information shall be submitted as part of the Business proposal.

A list of the last three contracts completed during the past three years and the last three contracts awarded currently in process that are similar in nature to the solicitation workscope.

Item 50: **Solicitation Provisions Incorporated by Reference:** The following provisions are applicable to this solicitation.

Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

III. Technical Proposal Instructions

Item 52: **Project Objectives, NIH-1688-1**, is applicable to this solicitation.

ADDITIONAL TECHNICAL PROPOSAL INFORMATION SPECIFIC TO THIS ACQUISITION

THE FOLLOWING INFORMATION IS SPECIFIC FOR PURPOSES OF RESPONDING TO THE RFP. THE OFFEROR SHOULD PAY CLOSE ATTENTION TO THE INFORMATION PROVIDED IN THIS SECTION OF THE RFP PACKAGE WHEN PREPARING THEIR PROPOSAL. THIS INFORMATION IS KEY TO THE EVALUATION OF PROPOSALS.

1) Mandatory Qualification Criteria

The offeror must include detailed information of how they meet the Mandatory Qualifciation Criteria (see Technical Evaluation Criteria). The information shall be provided in a separate section of the Technical Proposal that is labeled with the section heading, "Mandatory Qualification Criteria". Proposals in which this information is not provided or in which the information is not presented in the prescribed manner shall be returned to the offeror without review.

2) Methods and Approach

i. The offeror shall describe fully the DES-exposed cohort, including:

(1) detailing the initial requirements for inclusion in the cohort, including the basis for determining that DES exposure occurred;

(2) extent of data on the regimen of DES given to individual cohort members or to the typical member;

(3) total numbers of subjects initially eligible, losses to follow-up (by time, if possible), deaths (by time), and survivors;

(4) total number of exposed and unexposed daughters, sons and granddaughters to be followed, and number to be mailed questionnaires;

(5) proportion of subjects in (4) expected to respond to the questionnaire, and anticipated proportion that will require telephone interviews;

(6) occurrence of neoplasms in the cohort as measured to date and expected number that will occur over the next 5 years;

(7) extent of clinical data on cohort members from first and subsequent exams if applicable;

(8) extent of other data on cohort members from medical records, interviews or questionnaires if applicable;

ii. Additional information characterizing the cohort, the study base, and the data may include:

(1) description of a cohort of unexposed subjects selected to be comparable to men or women who were exposed in utero;

(2) special resources for confirming reported neoplasms;

(3) information on the accuracy and completeness of the study database; and

(4) other pertinent data about the study base.

iii. The offers shall describe methods to be used, including

(1) any plans to conduct feasibility efforts for the unbiased identification of previously unstudied subjects if, applicable, and discussion of tracing methods and maintaining contact with subjects. Eligibility for such inclusions will be limited to those with documented exposures (through medical records or confirmation by a physician who provided pre-natal care during the pregnancy), and those identified by prenatal record review. Identification of a new source of sons would be especially useful. The budget for this effort should be identified as a separate element;

(2) their understanding of key hypotheses to be evaluated in DES cohorts, and their priorities for future DES research. The NIH policy on women and minorities should be addressed providing required information and justification for exceptions to the policy;

(3) their willingness to participate in the pooling of nonidentified data from their cohort with those data from other participants in this effort, and their willingness to collaborate in studies that may be recommended by the Steering Committee.

(4) their approaches for gathering medical records, pathology reports and specimens, and any measures or precautions to be employed for shipment, storage and safe-keeping.

2) Personnel

Describe the experience and qualifications of personnel who will be assigned for direct work on this project. Information is required that lists the composition of the work group, the roles of each member in relation to the Statement of Work and a description of related qualifications of the members.

Indicate the approximate percentage of total time that each will commit to this project. For individuals who are not assigned 100% of their time, describe all current funding sources and commitments and how their commitment to the project will be assured.

Describe any levels of supervisory authority or provide a matrix to indicate the lines of supervision.

Provide complete, detailed resumes of the Principal Investigator and all other senior level personnel that indicate their educational background, recent relevant experience and profession accomplishments. Include dates, places, and names of previous employers and any related training. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment is required; a resume does not meet this requirement.

(1) Principal Investigator (M.D. or Ph.D. Level)

The Principal Investigator should have personal experience and familiarity with the clinical and research issues in the follow-up of people exposed to DES given in pregnancy.

(2) Project Manager (B.A. or M.A. Level)

The Project Manager should have personal experience supervising the collection of clinical or epidemiologic data and creating and maintaining the paper files and computer files needed in research.

(3) Technical Support Personnel

The following types of technical support may be required: tracing, abstracting, coding, data entry and electronic file preparation.

d) Collaborative Experience and Potential

Provide information concerning past collaborations and/or other evidence of the ability to collaborate in a large, multi-site cohort study.

3) Resources and Facilities

The offeror shall describe the available facilities and resources necessary to complete the project. The square footage of each space should be given and the extent of its dedication to this project indicated. Furnishings that are present in each space for use of this project should be described in sufficient detail, such as the size of tables and capacity of storage areas, to indicate their utility for the project A floor plan, drawn to scale, may be provided for each space to illustrate this detail. If space in a drawing is not 100% dedicated to this project, the percentage of availability should be clearly marked. Describe the location of each space relative to others and any logistics related to transportation, communication. Equipment should be described with model numbers, their location, availability for this project and key capabilities that are most pertinent to the project. Any computer software should be identified with version numbers. If availability of the facilities and equipment is not dedicated 100% to this project, the offeror should indicate availability relative to the work day and through what means that availability is assured to this project.

4) Organizational Structure and Experience

The offeror shall describe the organizational structure which will support the proposed studies and relevant experiences of the organization. Lines of responsibility and the relationship of the organization leadership to the personnel and resources that will support the proposed studies should be included in the Technical Prorposal. A flowchart may be used to help describe these relationships. The level of independence that is provided to personnel involved in monitoring quality control of the collected data should be explained. Experiences of the organization that are relevant to demonstrating capability should be described.

5) Discussion of Methods for Protection of Human Subjects

a) Identify the sources of research material obtained from individually identifiable living human subjects in the form of records or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing records or data.

b) Describe plans for the recruitment of subjects and the consent procedures to be followed, including the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. Describe what the approach to refusals will be.

c) Describe the procedures for protecting against or minimizing any potential risks, including risks to confidentially, and assess their likely effectiveness. Describe the provision for monitoring the data collected to insure the safety and privacy of subjects.

6) NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research

This research project involves human subjects. Offerors should make every effort to seek out and include, where feasible and appropriate, (a) women of all age groups; and (b) for studies in the U.S.A., racial/ethnic minority populations (American Indians or Alaskan natives, Asian or Pacific Islanders, African-Americans, Hispanics) in the study population.

Where inclusion of women and minorities is feasible, Offerors shall demonstrate how they will ensure that women and minorities are included in the study population.

Where inclusion of women and minority populations is not feasible, the offeror should submit with the technical proposal a brief but clear rationale for exclusions of one or both groups from the study population. The NCI will review the exclusion rationale in light of the research design. If the rationale is not considered acceptable by the Government, and the offeror is included in the competitive range, the offeror will be afforded the opportunity to further discuss and/or clarify his position during discussions and in the Final Proposal Revision (FPR). If the exclusion position is still considered unacceptable by the Government after discussions, the proposal may not be considered further for award.

7) Occupational Safety and Health

The offeror must outline potential biohazards to workers under this contract, particularly with regards to inadvertent needle stick injuries and must outline steps to be taken to minimize these risks.

No additional or supplemental Technical Proposal Instructions are applicable to this solicitation. See III. TECHNICAL PROPOSAL INSTRUCTION of SECTION L at http://rcb.cancer.gov/rcb-internet/wkf/sectionl.pdf for Technical Proposal Instructions.

IV. Business Proposal Instructions

Item 60: **Cost and Pricing Data** is applicable to this solicitation.

Subparagraph 3. Formats for Submission of Line Item Summaries:

[X] The format specified in SECTION L at http://rcb.cancer.gov/rcb-internet/wkf/sectionl.pdf is applicable to this solicitation.

[ ] The following format shall be used in lieu of the one specified in SECTION L at http://rcb.cancer.gov/rcb-internet/wkf/sectionl.pdf :*

*It is noted that the format specified above is also applicable to Alternate I, of FAR Clause 52.215-20, Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data.

Item 61: **Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data, FAR Clause 52.215-20**, is applicable to this solicitation.

Item 66: **Incremental Funding** is applicable to this solicitation.